K121211

JUN 27 2012

510(k) Summary

Manufacturer: Integra Spine, LLC
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Date Prepared: May 24, 2012

Device Trade Name: Integra Vu aPOD Intervertebral Body Fusion Device

Classification: §888.3080, Intervertebral fusion device with integrated fixation, lumbar

Class: II

Product Code: OVD

Predicate Device: Integra Vu aPOD Intervertebral Body Fusion Device (K101310)

Device Description:
The Vu aPOD Intervertebral Body Fusion Device consists of lumbar spinal interbody fusion devices as well as instrumentation designed specifically for the implantation of these devices. The Vu aPOD spacers are manufactured from PEEK OPTIMA LT1 polymer per ASTM F2026 while the bone screws and SpinPlate are comprised of Titanium alloy (Ti-6Al-4V ELI) per ASTM F136. Radiographic markers present with the Vu aPOD spacers are comprised of tantalum per ASTM F560. The Vu aPOD Intervertebral Body Fusion Device is for lumbar spinal use at one or two contiguous levels from the L2-L3 to L5-S1 disc levels.

Indications For Use:
When used with the bone screws, the Integra Spine Vu aPOD Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft material.

When used with the SpinPlate, the Integra Spine Vu aPOD Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft material. When used with the SpinPlate, the Integra Spine Vu aPOD Intervertebral Body Fusion Device is intended for use with supplemental fixation.

The Integra Spine Vu aPOD Intervertebral Body Fusion Device, when used with bone screws or bone screws and the SpinPlate, is a stand alone device. If the Integra Spine Vu aPod Intervertebral Body Fusion Device is used only with the SpinPlate then additional supplemental fixation, which has been cleared by the FDA for use in the lumbar spine, must be used to augment stability. This device is intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

Material Composition:
The Integra Vu aPOD Intervertebral Body Fusion devices are manufactured from Polyetheretherketone (PEEK-OPTIMA LT-1) per ASTM F2026 and Tantalum per ASTM F560. The bones screws and SpinPlate are manufactured from Titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

Comparison to Predicate Devices:
The technological characteristics of the Integra Vu aPOD Intervertebral Body Fusion Devices (with use of both fixation methods) are identical to all parameters with the exception of indications for use to the predicate device Integra Vu aPOD Intervertebral Body Fusion Device (K101310).

The subject device similarities include:

- The same design
- Indication for use with supplemental fixation
- Indication for use as a stand alone device
- The same materials
- The same sterilization process
- The same packaging configurations

Performance Standards:
Mechanical testing was performed per ASTM F2077 (static axial compression, static compress-shear, dynamic axial compression, dynamic compression shear), ASTM F2267 (static subsidence) and expulsion as part of standard design control activity, demonstrating that the Integra Vu aPOD Intervertebral Body Fusion Device (with use of both fixation methods) is substantially equivalent to the predicate device.

Clinical Testing:
There was no clinical or animal testing performed for this submission.

Conclusion: Integra Spine believes that sufficient evidence exists to add the indication for use of both methods of fixation in conjunction as a stand alone device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 27 2012

Theken Spine, LLC
% Mr. Dale Davison
Vice President of Engineering
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Medina, Ohio 44256

Re: K121211
Trade/Device Name: Vu aPOD Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: May 31, 2012
Received: June 01, 2012

Dear Mr. Davison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121211

Indications for Use

510(k) Number (if known): _K121211__

Device Name: **Integra Vu aPOD Intervertebral Body Fusion Device**

When used with the bone screws, the Integra Spine Vu aPOD Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft material.

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Prescription Use ___√___ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121211